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Examiner: Mary Hoffman

Applicant: Jorge L. Orbay

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DePuy Docket: DEP5692USNP

Title: Cap for Cut Metal Orthopedic Fastener

Honorable Commissioner for Patents
Alexandria, VA 22313

Sir:

PETITION FOR ONE MONTH EXTENSION OF TIME TO REPLY

The applicant hereby petitions the Commissioner for Patents for a one month extension of time to reply to an Office Action dated February 6, 2006. With the extension of time, the time for reply is extended to June 6, 2006 making this reply timely in nature. A $120 fee for the one month extension is required. In addition, one (1) independent claim and one (1) dependent claim have been canceled, and three (3) dependent claims have been added. A $100 fee for the additional claims is required. For the above, a total of $220 is enclosed. If any additional fee is due, please charge the fee to deposit account no. 07-1732.

ELECTION

The applicant hereby elects to prosecute without traverse the invention of the cap and nail (claims 1-24). The claims directed to the method (claims 25-26) are hereby canceled without prejudice as being drawn to a non-elected invention. Claims 27-29 have been added and read on the elected invention.

STATEMENT OF THE CLAIMS

1. (currently amended) A cap for a cut end of a nail, comprising:

a) a lead-in tubular portion having an inner surface which defines a first inner diameter;

b) an engagement tubular portion having an inner surface which defines a second inner diameter smaller than said first inner diameter, and an outer surface that defines an outer diameter that is at least four times a radial wall thickness of said cap at said engagement portion; and

c) a closed end at a proximal end of said engagement portion,

wherein said cap is manufactured from a plastic radiopaque material, and cap configured to be pushed over a cut end of a stiff orthopedic nail by a surgeon and retained to isolate the cut end of the nail from the anatomy.

2. (original) A cap according to claim 1, wherein:

said plastic is resilient.

3. (original) A cap according to claim 2, wherein:

said plastic is polyurethane.

4. (currently amended) A cap according to claim 1, further comprising:

d) an inner protuberance provided along said inner surface of said engagement portion, said inner protuberance defining a third inner diameter smaller than said second inner diameter.

5. (original) A cap according to claim 1, wherein:

said lead-in portion is cylindrical.

6. (original) A cap according to claim 5, wherein:

said engagement portion is cylindrical.

7. (original) A cap according to claim 6, wherein:

said engagement portion is longer than said lead-in portion.

8. (original) A cap according to claim 1, wherein:

said lead-in portion defines an inner diameter of approximately 0.080 – 0.092 inch.

9. (original) A cap according to claim 1, wherein:

said engagement portion defines an inner diameter of approximately 0.070 – 0.084 inch.

10. (original) A cap according to claim 1, wherein:

said cap has a length of approximately 0.285 - 0.310 inch.

11. (currently amended) A cap for a cut end of a nail, comprising:

a) a lead-in tubular portion having an inner surface which defines a first diameter;

b) an engagement tubular portion having an inner surface which defines a second diameter smaller than said first diameter;

c) an inner protuberance adapted to interfere with the nail when pushed on the nail so as to resist removal of the nail once the nail is inserted into said cap, said protuberance provided along said inner surface of said engagement portion and directed substantially radially inward; and

d) a closed end opposite said lead-in portion.

12. (original) A cap according to claim 11, wherein:

said cap is manufactured from a plastic radiopaque material.

13. (original) A cap according to claim 11, wherein:

said inner protuberance is a ring.

14. (original) A cap according to claim 13, wherein:

said ring has a convex outer surface.

15. (currently amended) A cap according to claim 11, wherein:

said engagement portion has an inner surface defining a third diameter smaller than said second diameter, wherein said second diameter is provided ~~distal~~ proximal of

said protuberance and said third diameter is provided ~~proximal~~ distal of said protuberance.

16. (original) A cap according to claim 11, wherein:

said lead-in portion has an inner diameter of approximately 0.080 – 0.092 inch.

17. (original) A cap according to claim 11, wherein:

said engagement portion has an inner diameter of approximately 0.070 – 0.084 inch.

18. (original) A cap according to claim 11, wherein:

said cap has a length of approximately 0.285 - 0.310 inch.

19. (currently amended) A cap for a cut end of a nail, comprising:

a resilient plastic cylindrically tubular element having a closed end and an inner surface, said tubular element having a wall with a radial wall thickness, an outer diameter at least four times said radial wall thickness, an inner diameter sized to be close fitting to the nail when pushed on the nail, ~~a length at least approximately three times said inner diameter,~~ and including an inner protuberance provided along said inner surface which frictionally engages the nail when pushed on the nail.

20. (original) A cap according to claim 19, wherein

said plastic includes a radiopaque material.

21. (original) A combination orthopedic nail and cap therefor, comprising:

a) a metal orthopedic nail having an end with a first diameter; and

b) a cap provided over said end of said nail,

said cap including a lead-in portion having an inner surface which defines a second diameter larger than said first diameter such that said lead-in portion is spaced apart from said end of said nail by a clearance, an engagement portion having an inner surface which defines a third diameter approximating said first diameter such that said engagement portion is substantially in contact with said nail, and a closed end.

22. (original) A combination according to claim 21, wherein:

said end of said nail is a non-passivated cut end.

23. (original) A combination according to claim 21, wherein:

said cap is manufactured from a plastic radiopaque material.

24. (original) A combination orthopedic nail and cap therefor, comprising:

a) a metal orthopedic nail having a first diameter and a cut end; and

b) a radiopaque cap provided over said cut end of said nail,

said cap including a plastic cylindrically tubular element having a closed end and an inner surface, said tubular element having an inner second diameter sized to be close fitting to the nail, a length at least approximately three times said second diameter.

25. – 26. (canceled)

27. (new) A cap according to claim 1, wherein:

an outer diameter of said cap at said engagement portion is approximately at least six times a wall thickness of said cap at said engagement portion.

28. (new) A cap according to claim 15, wherein:

said inner protuberance defines a fourth diameter, and said third diameter is larger than said fourth diameter.

29. (new) A combination according to claim 24, wherein:

said cut end has an end diameter, and said cap defines an opening for receiving said cut end, said cap at said opening having an outer diameter that is greater than said an end diameter.

REMARKS

The applicant does not understand the requirement for corrected drawing sheets. The Notice of Draftsperson's Patent Drawing Review indicates that the numbers and reference characters are not plain and legible. However, they appear plain and very legible. Nevertheless, in order to expedite allowance, replacement drawings have been submitted in accord with the Examiner's requirement.

Claim 15 stands rejected under 35 USC§112, first paragraph, as the Examiner states the claimed structure (third diameter slightly smaller than the second diameter) only exists when the cap is deformed by a nail and is not the normal structure of the cap. Claim 15 has been amended to correct the use of the terms "distal" and "proximal". In view of the correction and with reference to Fig. 4 and page 6, first paragraph, the third diameter H is slightly smaller than second diameter G when the nail is not present within the cap, "e.g., smaller by approximately 0.002 inch". Therefore, it is requested that this rejection be withdrawn.

Claims 1, 2, 4-7, 11, 12, 15 and 19-24 stand rejected under 35 U.S.C.§102(b) as anticipated by U.S. Pat. No. 5,885,227 to Finlayson. The applicant respectfully traverses the rejection for the following reasons.

Claim 1 is directed to a cap for a cut metal fastener. Finlayson teaches with respect to a tip for an arterial guidewire. The plastic tip 20 of the guidewire does not read on the claimed cap for the following reasons. Claim 1 has been amended to state that

the outer diameter at the engagement portion has a dimension at least four times the wall thickness at the engagement portion. This limitation is supported in the Specification at page 5, line 6 – page 6, line 8. In view of the given exemplar inner and outer dimensions described, the wall thickness at various locations along the cap is defined. The so-called 'engagement portion' of Finlayson has a diameter that is approximately twice the wall thickness in view of the very small diameter of the section of wire 12d.

Claim 4, as amended, requires an inner protuberance along the engagement portion of the cap that defines a third inner diameter smaller than the second inner diameter of the engagement portion. The portion of the tip of the guidewire identified by the Examiner (i) is not a protuberance, but rather a simple step-up transition between two portions of stepped diameter, (ii) is not along the engagement portion, and (iii) does not define a third inner diameter smaller than said second inner diameter. Furthermore, if such identified portion (the proximal portion of 12d) is a protuberance, it is the exact same structure as the engagement portion. This same structure does not read on two differently defined structures of the claimed invention.

Similarly to claim 4, claim 11, as amended, includes limitations with respect to the inner protuberance which clearly distinguishes the cap from the tip of the guidewire. The inner protuberance is stated (i) to be "adapted to interfere with the nail when pushed on the nail so as to resist removal of the nail once the nail is inserted into said cap" and to be (ii) directed substantially radially inward. The tip of Finlayson fails to meet these limitations. The coupling between the tip 16 and core 20 in Finlayson requires a

combination of heating and compression to work the tip into the windings of coil 16 or the use of an adhesive. (col. 3, lines 49-62). It is not coupled with an interference fit. Neither of Finlayson's described couplings is acceptable for the intended application of the claimed invention, and an interference fit does not provide the engagement required for Finlayson's purpose.

Claim 15 claims with respect to the relative inner diameters as shown at D, G, and H in Fig. 4 and described at page 5, line 16 – page 6, line 8. Finlayson fails to teach or suggest such relative dimensions.

Claim 19, as amended, requires the cap have a wall with a radial wall thickness, an outer diameter at least four times said radial wall thickness. The Finlayson tip has a very thick radial wall. The outer diameter is substantially less than four times the radial wall thickness. There is no suggestion to reduce the thickness of the wall (so that the outer diameter would be at least four times the wall thickness) in Finlayson to track the core 12 as the core reduces in diameter. Finlayson states that as the core reduces in dimension it is desirable to have the tip maintain the same diameter as the remainder of the guidewire: "The guidewire thus has a uniform diameter from its proximal end 11 to its distal end 26." (col. 3, lines 57-58)

Claim 21 requires a metal orthopedic nail. An orthopedic nail is a limitation by definition. Such nail must have the stiffness to stabilize and support a fractured bone. The guidewire in Finlayson is designed for very high flexibility, to be snaked through

arteries. It is clearly not intended for any orthopedic stabilizing or support purpose, has no such structure, and is not an orthopedic nail. In addition, the claim requires that the lead-in portion of the cap be spaced apart from said end of said nail by a clearance. In Finlayson, the cap 20 is in contact with core 12 along its entire length. Furthermore, with respect to claim 22, the nail is required to have a non-passivated cut end. This is not a "cutting end", as mischaracterized by the Examiner. As clearly set forth in the Specification, small diameter orthopedic nails, e.g., K-wires are often inserted into bones. Such nail is "passivated" to increase corrosion resistance and reduce reactivity in the human body. Passivation creates a relatively non-reactive thin oxide film over the outer surface of the metal. However, such nail may need to be cut down in length during implantation which exposes a reactive non-passivated cut end of the nail to the body. It is this non-passivated cut portion of the nail over which the cap is positioned. Finlayson fails to teach or suggest anything in relation to the claimed combination.

Claim 24 also requires a metal orthopedic nail having a cut end and a cap provided over the cut end of said nail. For reasons advanced above, Finlayson fails to teach or suggest the claimed invention.

Claims 8-10 and 16-18 stand rejected under 35 USC § 103(a) as unpatentable over Finlayson. Such claims are directed to particular preferred dimensions for a cap for a cut metal orthopedic fastener. The Examiner argues that while the claimed dimensions are not shown by Finlayson, they are simply different optimum dimensions for use in another area of the body and not patentable in view of *In re Aller*. The applicant

traverses this rejection. The Finlayson tip is not a cap for a cut metal fastener; it is a tip for a guidewire. The Finlayson tip has three purposes: (1) to provide a traumatic blunt tip to a leading end of an advancing arterial guidewire (col. 2, lines 48-51), (2) to provide a uniform diameter along the entire length of the guidewire (col. 2, lines 52-54; col. 3, lines 57-58), and (3) to provide imaging during an interventional catheterization procedure such as angioplasty (col. 1, lines 11-14; col. 4, lines 32-35) so that the moving end of the guidewire is known. In distinction, the claimed cap is (1) to seal the non-passivated cut end of an orthopedic nail to prevent negative chemical reaction within the human body (Spec. at page 2, lines 18-20); (2) to reduce friction of skin against an end of a stationary nail to reduce irritation and inflammation and thus pain (Spec. at page 2, lines 20-22), and (3) to allow fluoroscopic location of an end of the fully seated implanted nail so that it can be located at a later time and not during the current procedure (Spec. at page 2, lines 9-10; page 3, lines 1-3). Given the completely different intended purpose of the claimed invention relative to Finlayson, Finlayson is clearly non-analogous art, and *In re Aller* is not applicable. *In re Aller* would be applicable if applicant were claiming a guidewire and/or its tip with dimensions other than shown by Finlayson, but that is clearly not being claimed. The claimed dimensions are not optimal to one skilled in the art in view of the stated purpose of Finlayson.

For the foregoing reasons, all the claims are allowable over the art of record.

Claims 27-29 reading on the elected invention have been added to more completely claim the invention.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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